Remarks

As the Examiner correctly noted in the Office Action of June 22, 2004, claims 20, 22-36, 36-48 and 50 were canceled in the amendment of November 28, 2003. Claims 41-49 and 51-64 are being canceled herein without prejudice. New claims 65-91 are being added herein for clarity for the reasons set forth below.

In the Amendment filed on June 19, 2002 in the parent case, and in response to the restriction requirement under 35 U.S.C. § 121 set forth in the Office Action dated December 19, 2001, claims 1-19 were withdrawn without prejudice as being drawn to a non-elected invention.

Independent claim 20 was amended in the Supplemental Amendment filed on August 1, 2002 consistent with the Examiner's suggestion during the interview of July 11, 2002 to change the term "comprised" to "consisting essentially" to overcome the 35 U.S.C. § 103(a) art rejection over US Patent No. 5,635,204 to Gevirtz et al (the '204 patent). Applicant hereby acknowledges the previous *withdrawal* of this rejection by the Examiner in the Office Action dated August 20, 2002.

Because, claims 20, 22-35 were canceled in the amendment of November 28, 2003, without prejudice, new claims 65-79 have been added herein for clarity and to enhance the efficient prosecution of this application to issue. New claims 65-79 correspond to the preciously allowable claims 20 and 22-35. In particular, new claim 65 corrects the inadvertent typographical error that appeared in claim 20 as originally presented and thereby omits the misspelled term "chlondine" from the claim. This amendment is believed to overcome the Examiner's rejection under 35 U.S.C. § 112, second paragraph. Independent claim 20

was also previously amended on February 20, 2003 to include the limitations of dependent claim 21 (namely to limit claim 20 a specific group of guanidine derivatives) and, accordingly, dependent claim 21 was canceled at that time. Likewise, these amendments are reflected in the newly presented claim 65.

Dependent claims 66-79 also correspond to the previously allowable claims 22-35. For the reasons set forth below, Applicant believes that new claims 65-79 (which correspond to the previously allowable claims 20 and 22-35) are in condition for allowance.

New claims 80-91 are being added and correspond to previously canceled claims 36, 38-48. Independent claim 36 was previously amended on February 20, 2003 to include the limitations of dependent claim 37 (namely to limit claim 36 to a specific group of guanidine derivatives) and, accordingly, dependent claim 37 was canceled at that time. Newly added claim 80 corresponds to the earlier amendments to claim 36. New claim 80 also corrects an inadvertent typographical error and thereby omits the misspelled term "chlondine" from claim 36. This amendment is believed to overcome the Examiner's rejection under 35 U.S.C. § 112, second paragraph.

Thus, as set forth in the "Amendments to the Claims" above, claims 65-91 are currently pending in the application. The above amendments and the following remarks are believed to place the application in condition for allowance.

Objection to the Specification

As set forth on page 2 of the instant Office Action, the Examiner's objection to the specification is maintained with respect to Tables 1-3. In particular, the Examiner states that

Tables 1-3 contain graphs that should be deleted from the specification and resubmitted as drawings. A section titled "Brief Description of the Drawings" should be added to the specification. MPEP 608.01 cites 37 CFR 1.58 "Chemical and mathematical formulae and tables" which recites that drawings may not be included in the specification. The Examiner notes Applicant's intent to amend the specification and submit formal drawings to replace Tables 1-3 upon receipt of a notice of allowability of the claimed invention.

In addition, the Examiner had previously objected to the disclosure and claims because of the following: compounds "clonidine" and "atipamezole" appear to be misspelled. Applicant will correct the spelling errors of the specification as required by the Examiner at the time of the correction of the specification to include formal drawings of Tables 1-3 and add the "Brief Description of the Drawings" is made (upon receipt of the notice of allowability). Applicant appreciates the Examiner's understanding and cooperation in this matter.

Rejection under 35 U.S.C. § 112

New claims 65-91 contain the previous amendments to claims 20, 22-36 and 38-48 and are believed to render the rejections under § 112 moot. In view of the newly presented claims 65-91 withdrawal of the rejections under 35 U.S.C. § 112, are believed to be warranted.

Rejection under U.S.C. § 103(a)

As stated above, but repeated here for clarity, new claims 65-91 correspond to claims 20-48 which were previously canceled without prejudice and the agruments that were previously

presented and accepted by the Examiner are equally applicable to the newly presented claims 65-91. In particular, as stated in the Office Action dated May 23, 2003, claims 20, 22-36, and 38-48 were rejected under 35 U.S.C.§ 103(a) as allegedly being unpatentable over US Patent 5,635,204 alone or in view of Veterinary Pharmacology and Therapeutics (Adams). However, during the telephone interview with the Examiner of December 4, 2003, the Examiner noted that the § 103(a) rejection of claims 20 and 22-35 in view of the '204 patent (originally set forth in the Office Action dated December 19, 2001) was previously withdrawn (*see*, page 3 of the Office Action dated August 20, 2002).

This rejection was specifically withdrawn by the Examiner in response to the interview of July 11, 2002, and the agreement reached therein to amend claim 20 to limit the claim to compositions consisting essentially of a guanidine derivative. As recognized by the Examiner, none of the cited references including the newly cited Veterinary Pharmacology and Therapeutics (Adams) teach or suggest the use of a single guanidine derivative for inducing a rapid onset sedation and analgesia in an animal.

With respect to claims 20 and 22-35, (new claims 65-79) there is absolutely no teaching or suggestion anywhere in the '204 patent or in Adams of a method of rapid induction of long lasting sedation and analgesia via administration of a single guanidine derivative as set forth in independent claim 20. The use of a single guanidine derivative selected from the group set forth in amended claim 20 certainly cannot be obvious based upon the teachings of the '204 patent and Adams.

U.S. Patent No. 5,635,204 is directed to the use of a *required combination* of drugs to induce *general anesthesia* or a

surgical stage of anesthesia in a recumbent individual. The specification of the '204 patent at column 2, lines 9-23 specifically recites the required combination of drugs for induction of *general anesthesia*, namely fentanyl or a fentanyl analog (line 12); an α_2-adrenergic agonist such as clonidine (lines 13-16); and an amnesia inducing drug such as ketammine (lines 17-19). General or surgical anesthesia places an animal in recumbancy and increases the risk to the patient and, as set forth in the '204 patent, *requires* administration of additional drugs, namely narcotics and dissociative anesthetic agents such as fentanyl and ketamine respectively, which increase the risk of adverse reactions in the patient. The methods of claims 20 and 22-35 (new claims 65-79) do not require administration of any agent other than a guanidine derivative for induction of the desired sedation and analgesia. The induction of the desired sedation and analgesia cannot be obvious in view of the teachings of the '204 patent.

Likewise, Adams, teaches that the alpha adrenergic agonists are used as preanesthetic agents (See, Table 9.9 (4)) and are advocated as such where "the concurrent use of two or three drugs is usually required to accomplish the required preanesthetic conditions in the patient" and Adams notes that "unfortunately, preanesthetic medication is not without its complications" (See, page 160, column 2). Thus, Adams teaches the use of alpha adrenergic agonists such as Xylanine for use as a preanesthetic agent for which a subsequent drug is administered to achieve the desired anesthetic effect as is required in the '204 patent. Neither reference teaches or suggests the of a single guanidine derivative as set forth in independent claim 20 (new claim 65). Therefore, withdrawal of the rejection of claims 20, and 22-35 under § 103(a) is believed to continue to

be warranted and allowance of the corresponding new claims 65-79 is respectfully requested.

The above remarks are equally applicable to claims 36 and 38-48 (new claims 80-91) which were also rejected in the instant office action under § 103(a) over the '204 patent alone or in view of Adams. Claims 36 and 38-48 (new claims 80-91) are directed to a method for inducing rapid onset and long lasting sedation and analgesia in a standing equine animal which further distinguishes over the cited art. There is no teaching or suggestion of the use of a quanidine derivative in a single administration to a standing equine animal to achieve the desired effect.

Accordingly, in view of the previous amendment of claims 20, 22-36 and 38-48 which are reflected and presented in the newly added claims 65-91, withdrawal of the rejection of under 35 U.S.C. § 103(a) is believed to be warranted and is earnestly solicited.

Related Matters

The Assistant Commissioner is hereby authorized to debit Deposit Account No. 19-4430 the amount of $ 510.00 for the fee for a three month extension of time. No additional fee is believed to be due at this time, however, the Commissioner is hereby authorized to debit deposit account number 19-4430 for any additional fees deemed to be due or issue a credit for any overpayment thereof. The Examiner is encouraged to contact the undersigned attorney directly if such

contact will enhance the efficient prosecution of the application to issue.

Respectfully submitted,

KING AND SCHICKLI, PLLC

J.W. Seanor, D.V.M.
Registration No. 40,804

247 North Broadway
Lexington, KY 40507
(859) 223-3400

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as Express Mail on the date listed below in an envelope addressed to: Commissioner for Trademarks, 2900 Crystal Drive, Arlington, Virginia 22202-3514.

12-22-04
Date

Amy L. Shouse